UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION

Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

RESPONSE TO PLAINTIFFS' MOTION TO COMPEL DISCOVERY AND FOR EXPEDITED HEARING

Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson ("J&J") (collectively, "Defendants") hereby respond to Plaintiffs' "Motion to Compel Discovery and for Expedited Hearing" (Doc. 584) (the "Motion").

I. There is no Discovery Dispute Regarding the Majority of the Seven Arguments Raised in Plaintiffs' Motion to Compel. For the Remaining Topics the Dispute is not Whether the Plaintiffs are Entitled to Discovery on that Topic but Rather Whether the Topic is the Proper Subject of a 30(b)(6) Deposition.

The proper purpose of discovery motion practice is to present to this Court discovery disputes in which a requesting party seeks legitimate discovery but the responding party refuses to produce that information without Court intervention. For the majority of the seven topics that are the subject of this Motion, Plaintiffs have improperly certified to this Court that there is a dispute requiring Court intervention as required by L.R. Civ. P. 37.1(b). And although there are disputes regarding a few of the remaining topics, those disputes are not a result of Defendants being unwilling to produce the requested information, but rather disagreement as to whether the specific topic at issue is a proper subject of a 30(b)(6) deposition as opposed to some other form of discovery.

Plaintiffs' Motion seeks relief in regard to the following seven areas:

Arguments A & G: Plaintiffs seek the production of what they describe as "Standard Operating Procedures." There is no dispute regarding the production of these procedures. As explained below, Plaintiffs' Motion does not inform this Court that: (a) this exact issue has been the topic of numerous conversations and negotiation since the Defendants' Objections were filed on April 10, 2013¹; and (b) *before* this Motion was filed, the Defendants agreed to produce the very Procedures that allegedly could not be obtained without Court intervention and which are the subject of Arguments A & G in this Motion. Pursuant to this agreement, the procedures sought by Plaintiffs were produced to them on Friday, May 10, 2013, and Monday, May 13, 2013. Thus, the only remaining dispute regarding this topic is whether the Plaintiffs are required to comply with Rule 30(b)(6)'s mandatory requirement that the Notice "must describe with reasonable particularity the matters for examination" or whether the Plaintiffs are entitled to question a corporate designee on over 180 procedures, some of which have up to 20 different revisions, without giving counsel or the designee any guidance on the specific areas of inquiry.

Argument B: Plaintiffs seek to force the corporate designee to testify about the Bates Stamps ranges for voluminous documents that were not collected by that witness, stamped by that witness, or produced by that witness. There is no dispute that before this Motion was filed, Defendants agreed to produce this information to the Plaintiffs in the form of a written discovery response. Thus, the dispute before this Court is not whether the information will be provided, but whether it is a proper subject for a 30(b)(6) deposition.

¹ In fact, as will be set forth in Section III.A, counsel for the Defendants has sent numerous emails to the Plaintiffs during the period of April 9, 2013, to May 9, 2013, documenting progress on the production of the requested documents.

Argument C: Plaintiffs seek the identification of members of the Product Development Team for the TVT Products. Defendants have already produced the discovery that identifies the individuals who designed these products. Thus, the dispute before this Court is not whether the information will be provided—it has been—but whether it is a proper subject for a 30(b)(6) deposition.

Argument D: Plaintiffs seek the disclosure of the "product names" for the Devices. There is no dispute regarding this topic. Before this Motion was filed, Defendants had already agreed to produce the information requested. Defendants' corporate designee will be prepared to testify to the product names at the deposition.

Argument E: Plaintiffs seek information regarding the patents for the TVT Devices. Plaintiffs' Motion fails to inform this Court that before this Motion was filed, Defendants had already agreed to produce the information requested in regard to the United States patents, and Defendants' corporate designee will be prepared to testify about these patents "from a design perspective" at the deposition. Defendants agree that there is a dispute regarding the production of information regarding ex-US patents but disagree that it should be part of this Expedited Hearing.

Argument F: Plaintiffs seek testimony regarding the design control and validation of the manufacturing processes, including, but not limited to, heating, extrusion, annealing, cooling, gamma radiation, and sterilization. Defendants have agreed to produce a witness to address these topics. No dispute exists that requires the Court's intervention.

In sum, as will be explained in greater detail below, the only disputes properly before this Court in the Motion are: (a) whether, in regard to Topic A, Plaintiffs' Notice describes the subject matter with reasonable particularity as required by Rule 30(b)(6); (b) whether, in regard

to topic B, an offer to provide a written discovery response in lieu of deposition testimony is insufficient; and (c) whether, in regard to Topic C, Defendants have met their discovery obligation or are required to do more. All of the other alleged disputes were resolved prior to the filing of Plaintiffs' Motion, except for the issue of the production of ex-US patents (which should not be a subject of this expedited hearing).

II. The Procedural Propriety of Plaintiffs' Motion and Defendants' Objections

As set forth above, Defendants do not agree that a number of the grounds set forth in Plaintiffs' Motion are proper, because they do not comply with L.R. Civ. P. 37(b)(1), which requires the moving party to have narrowed the areas of disagreement to the greatest possible extent. In fact, for a number of the areas, there is no disagreement at all and thus no basis for a motion to compel. Additionally, with the exception of the production of the design procedures issue (which has been the subject of numerous communications since April 10, 2013, as Defendants attempted to identify the specific procedures sought by Plaintiffs), Defendants do not recall, and have found no correspondence addressing, any follow-up from Plaintiffs after the Objections were filed on April 10, 2013, until Thursday morning (May 9, 2013), when Plaintiffs sent Defendants a draft of the Motion to Compel and made an ultimatum that either all objections be dropped or the Motion to Compel would be filed that day.

Notwithstanding Defendants' repeated efforts to resolve the discovery disputes without Court intervention, Plaintiffs argue in their Motion that Defendants' objections to the Rule 30(b)(6) deposition notices are improper under the Federal Rules of Civil Procedure. *See* Motion at 3. They cite a decision from the District of Massachusetts for the proposition that the only way to limit the scope of a Rule 30(b)(6) deposition is to seek a protective order pursuant to Rule

26(c). *Id.* (citing New England Carpenters Health Benefits Fund v. First DataBank, Inc., 242 F.R.D. 164, 165-166 (D. Mass. 2007)).

Two weeks after Defendants filed their response and objections to the Rule 30(b)(6) notices, this Court issued its memorandum opinion and order in *Robinson v. Quicken Loans, Inc.*, No. 3:12-cv-00981, 2013 WL 1776100 (S.D. W. Va. April 25, 2013). In *Robinson*, this Court observed that "[w]hen a corporation objects to a notice of Rule 30(b)(6) deposition, the proper procedure is to file a motion for protective order." *Id.* at *3. For support, the Court cited the same District of Massachusetts case on which Plaintiffs now rely. *Id.* (citing *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 242 F.R.D. 164, 165-166 (D. Mass. 2007)).

This matter differs from *Robinson* in two key respects. Most importantly, *Robinson* involved a motion to compel made *after* a Rule 30(b)(6) deposition at which a party (Quicken Loans) instructed its witness not to testify based on certain objections Quicken Loans had lodged days earlier; by contrast, the instant dispute concerns a pre-deposition motion to compel aimed at clarifying the propriety of the topics and requests of Plaintiffs' Rule 30(b)(6) notices. This is a critical distinction. Even those courts that have held—like this Court did in *Robinson*—that a party cannot rely upon formal objections to noticed Rule 30(b)(6) topics as a reason for instructing a witness not to answer specific questions on the disputed topic (or as an excuse for failing to produce a designated witness altogether) have concluded that a party can rely upon formal objections to the noticed Rule 30(b)(6) topics in opposing a motion to compel filed pursuant to Rule 37(a). *See*, *e.g.*, *Lykins v. Certainteed Corp.*, No. 11-2133-JTM, 2012 WL 3542016 at *4 (D. Kan. Aug. 16, 2012). After all, the justification for requiring an objecting party to file a motion to compel is to allow the court to determine *before* a deposition whether the

notice is objectionable or insufficient. *See Robinson*, 2013 WL 1776100 at *3 ("Consequently, once a Rule 30(b)(6) deposition notice is served, the corporation bears the burden of demonstrating *to the court* that the notice is objectionable or insufficient."). That goal is achieved in those instances where the matter is brought to the court's attention after one party lodges objections and the other party moves to compel. Accordingly, notwithstanding the Court's ruling in *Robinson*, Defendants respectfully submit that, from a procedural standpoint, the dispute at hand has been properly presented to the Court for determination.²

This matter also differs from *Robinson* factually. In *Robinson*, Quicken Loans waited until three days prior to the noticed deposition to lodge its objections to the deposition topics, notwithstanding the fact that the plaintiff had notified Quicken Loans of the deposition topics more than three months earlier. Quicken Loans took no other action with respect to its objections, instead content to produce a corporate witness to testify to those topics as to which Quicken Loans had no objection. Here, Defendants notified Plaintiffs of their objections to the deposition topics shortly after receiving notice of the same and attempted to engage in a meetand-confer process to resolve the parties' disputes. Consequently, because Defendants' objections were made in a good faith effort to resolve valid discovery disputes, the Court should consider the merits of those objections in assessing Plaintiffs' Motion, even if the Court decides that the objections should have been raised pursuant to a Motion for Protective Order.

² If this Court concludes that Defendants have used an improper procedural vehicle, then Defendants do request that the Court provide guidance as to how in the future they should raise objections to Plaintiffs' deposition notices.

III. Argument

a. Topic a ("Standard Operating Procedures")

Topic "a" seeks deposition testimony concerning the "Standard Operating Procedures (SOP) associated with the design and development of the [TVT] Devices." Plaintiffs maintain that they are entitled to each version of the design and development SOPs and to question Defendants' designees about all versions of the design and development SOPs so that Plaintiffs can discover what SOPs were in effect at all relevant times.

1. Plaintiffs Omit the Substantial Efforts Defendants Have Employed to Produce the SOPs as the Result of a Month of Meet and Confers.

Significantly, Plaintiffs represent to this Court that "Defendants have still not agreed to produce all of the relevant design and development SOPS, including the effective dates, the revision history, and the dates of the revisions." [584, p. 5] As will be shown below Plaintiffs' contention omits numerous material facts.

In the 120+ discovery productions that have occurred to date in this case, Defendants have produced thousands of pages of procedures and other documents. [cf., 517, pp. 29-30]. And for more than a month, Defendants have been working with Plaintiffs to produce all requested SOPs that relate to product design. Specifically, on March 28, 2013, counsel for Defendants sent counsel for Plaintiffs a list of 891 procedures based on a search that revealed numerous design and development SOPs, and asked counsel for Plaintiffs to identify which SOPs he would like copies of. (A true and correct copy of the correspondence and spreadsheet is attached hereto as Ex. A.) Counsel for Defendants agreed that they would produce all revision histories (which in many cases can be multiple documents) as well as the effective dates of each revision.

Nearly a month later, on April 23, 2013, counsel for Plaintiffs sent Defendants a list of 181 SOPs that they wanted. (A true and correct copy of this correspondence is attached hereto as Ex. B.) Since then, Defendants have been diligently working to obtain these SOPs and all revisions. Defendants have devoted substantial resources to this effort, including four people to locate and pull the revisions. As a result of this effort, Defendants sent the first installment of the 181 SOPs to counsel for Plaintiffs via secure file transfer on May 10, 2013. This consisted of approximately 296 documents and 4,687 pages. (A true and correct copy of the production letter is attached hereto as Ex. C.) The second and hopefully final installment is scheduled to be produced to Plaintiffs on May 13, 2013.³ This production is expected to be an equally substantial volume of documents to complete the production of the SOPs requested by Plaintiffs.

Accordingly, by the time this motion is heard, Defendants expect they will have provided to Plaintiffs each of the 181 SOPs selected by them on April 23, with the effective dates, the revision history, and the dates of the revisions.

2. Identifying the Relevant SOPs and Producing all Prior Versions is a Complex and Time Consuming Undertaking.

Additionally, in their Motion, Plaintiffs assert that, during the deposition of Susan Lin, they were "surprised" to learn of SOPs and the fact that they have revision histories. This feigned surprise is belied by the facts. Throughout the production of documents in this case, numerous SOPs have been produced. [517, pp 29-30] Each SOP clearly states its revision

³ At the time of the filing of this brief, Defendants continue to work on the documents to be produced on May 13, 2013. Despite Defendants' best efforts, there may be some SOPs that do not make it into the production. As a result, Defendants may need to produce additional SOPs to Plaintiffs on May 14, 2013.

number, and in most cases, includes a summary of the revision history. For Plaintiffs to suggest that they just learned of these facts is incorrect.

On page 5 of their motion, Plaintiffs assert that it is very "easy" for Defendants to identify and produce all of the design and development SOPs. This is not the case. The databases that store the SOPs span three document systems; and the TVT Devices have been sold for more than fifteen years, thus encompassing multiple revisions, sometimes more than twenty for a single procedure. Additionally, the current document management system, the Adaptiv system, contains at least 98,000 documents. Nevertheless, in support of their argument, Plaintiffs offer a quote from the deposition testimony of Bryan Lisa. Mr. Lisa is a former employee, who worked at the company prior to the adoption of the Adaptiv document management system, who worked in the Regulatory Affairs department, and who was not tasked with the responsibility of managing the 98,000 documents in the Adaptiv system. The import of Mr. Lisa's testimony is that if one knows the particular SOP (perhaps by identifying number), it is not a difficult process to locate it in the database. This does not tell the whole story. What Mr. Lisa did <u>not</u> testify to is that "all SOPs" related to a particular issue are readily identifiable. There is no "master index" of SOPs, so it is a far more difficult task than Plaintiffs suggest.

Counsel for Defendants have been very clear throughout all of the meet-and-confer process about the burden inherent in identifying design and development SOPs. Ultimately, Defendants believe they have produced all documents (plus prior versions and revision histories) for procedures related to design, rendering this aspect of the Motion moot. Finally, as noted by counsel for Plaintiffs in their May 8, 2013, correspondence, Defendants continue to seek to meet and confer with Plaintiffs to find the best solution to the overall SOP issue.

3. As set forth in Defendants' Objections, this is an Improper Topic for a 30(b)(6) Deposition

In the Objections, Defendants explained why this is an improper topic for a 30(b)(6) deposition:

Federal Rule of Civil Procedure 30(b)(6) requires that the deposition notice "describe with reasonable particularity the matters for examination." The purpose of this requirement is to permit the deponent to be able to prepare properly for the deposition, as the deponent may be asked to testify on matters outside of his or her personal knowledge. Defendants object that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The design and development of the Devices were long-term projects, taking a total of more than a dozen years from TVT to TVT Exact and Abbrevo. Thus, the Standard Operating Procedures associated with each device were revised multiple times over the course of this period. Defendants object that: (a) it is impossible for any witness to testify about every version of the Standard Operating Procedure associated with each device; (b) this topic is overbroad since there will be numerous standard operating procedures applicable to the design of the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular standard operating procedures that Plaintiffs seek to discover.

[517, pp. 2-3].

Defendants stand by this objection. As set forth above, over 180 procedures have been produced that relate to the design of products at Ethicon, many of which have numerous revisions. If the Plaintiffs wanted to identify a particular procedure to question a witness about, that would be one thing. But to merely state that all procedures and all revisions are a proper subject for questioning violates Rule 30(b)(6)'s mandatory requirement that the topic be described with reasonable particularity. *See, e.g., Catt v. Affirmative Ins. Co.*, No. 2:08-CV-243, 2009 WL 1228605 at *5 (N.D. Ind. Apr. 30, 2009) (finding deposition topic that sought "general testimony about the documents produced [in discovery] does not satisfy the 'reasonable particularity' requirement'). If Defendants are ordered to produce a witness to address this topic

as it stands, a witness will be faced with an impossible task—the witness will be tasked with answering questions about hundreds of documents, with multiple revisions, with no ability to prepare for the actual documents that will be the subject of inquiry. No witness could properly do this, and Rule 30(b)(6) does not require it.

b. Topic b (Design History Files)

Topic "b" seeks testimony regarding the complete design history file ("DHF") for each of the TVT devices. A DHF is a compilation of documents that relate to the design of the product. Each DHF for each of the products encompasses multiple volumes, and each file can comprise thousands of pages.

In response to this topic, the Defendants objected on the basis that the topic was overbroad and failed to provide the requisite particularity required by Rule 30(b)(6). The parties engaged in the meet-and-confer process, and Plaintiffs narrowed their request to seek information regarding five aspects of each DHF as follows: (1) what makes up the Design History File ("DHF"); (2) what are the component parts of the DHF; (3) the custodian of the DHF; (4) how the DHF is maintained; and (5) the Bates ranges for each DHF. Of these five items, Defendants agreed to produce a witness to testify in regard to the first four and stated that they were willing to provide a written response regarding the fifth. Plaintiffs have rejected this offer, and the parties' only dispute concerns whether providing the written response for the fifth item is sufficient or whether Defendants' 30(b)(6) designee must testify to the Bates ranges for each DHF.

Put simply, the Bates range for each DHF is not a proper topic of a Rule 30(b)(6) deposition. Plaintiffs argue in their motion that, by this item, they want to "ensure accuracy and completeness" of the DHFs provided. In the objection, Defendants offered and remain willing to

provide a written discovery response that identifies the Bates ranges of each DHF.⁴ Providing a written response to this topic will satisfy any concern Plaintiffs might have about the completeness of the DHFs produced. Plaintiffs have failed to identify a single reason why receiving this information in the form of a written response that identifies the Bates ranges is insufficient to satisfy their concerns or why it is necessary that such information be provided solely in the form of witness testimony from the 30(b)(6) designee on design topics. This is particularly non-sensical since the witness will not have collected the documents, Bates stamped the documents, or produced the documents. And while in an isolated situation it might not matter if a witness was asked to assess whether a short document is a complete copy, a witness cannot be forced to do this when the documents in their entirety comprise many thousands of pages. This is more properly handled through a written response rather than witness testimony by the corporate designee, and Plaintiffs' motion with respect to Topic b should be denied.

c. Topic c (Product Development Team)

Topic "c" seeks deposition testimony concerning "Members and procedures of the Product Development Team for the [TVT] devices." Defendants objected, stating:

Defendants object that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The design and development of the Devices were long-term projects; the members and procedures of the Product Development Team for the Devices changed over time encompassing more than twelve years; and this information is reflected in the design history files—which encompass more than ten thousand pages of material. It is impossible for any witness to testify about the members and procedures of the Product Development Team for seven products. Defendants further object that this topic is vague and ambiguous. Due to the long-term nature of the projects, as well as the fact that

⁴ This written response could be in the form of an Interrogatory response that would be verified or in the form of a document production request that set forth the Bates stamp ranges of the individual DHFs, stating, for example, that documents Eth.Mesh. __ to Eth.Mesh __ comprise the DHF for TVT (or TVT-O, etc.).

many individuals played only a tangential role in those projects, various witnesses may consider the same individual to be "on" or "not on" the design team for a particular device. Finally, Defendants object that the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the design history files, which Defendants have already produced to Plaintiffs as they were kept in the ordinary course of business and in an electronically searchable format.

[517, pp. 4-5].

Defendants stand by this objection. In order to answer Plaintiffs' proposed questioning, Defendants' corporate designee would have to memorize the Design History Files, which collectively comprise many thousands of pages of documents. This is more than an undue burden; it is impossible. *See*, *e.g.*, *Catt*, 2009 WL 1228605 at *5 (finding deposition topic that sought general testimony about documents produced too broad, not described with reasonably particularity, and unduly burdensome). And the information is equally available to the Plaintiffs and is set forth in the Design and Development Plans, Team meeting minutes, and lab reports, all of which have been produced to the Plaintiffs. *See* Fed. R. Civ. P. 26(b) (providing that all discovery, including Rule 30(b)(6) depositions, may be limited if court determines that it "can be obtained from some other source that is more convenient, less burdensome, or less expensive").

Additionally, there are substantive problems with Plaintiffs' proposed topic as well. For example, the designee would be forced to guess whether under Plaintiffs' definition, a person is or is not on the team. And the team changes—Ethicon is a large company and one of its strengths is that it can draw upon the expertise of individuals from multiple areas within the company. Some of these individuals may work on a project from start to completion; some may work on it for only a short period. For that reason, Plaintiffs' motion to compel with respect to Topic c should be denied.

Despite the fact that this topic is improper, Defendants want to make sure that the Court understands that this does not mean Defendants will not provide information on this subject to the Plaintiffs, when such information is sought in a proper way. For example, the corporate designee will be able to answer questions on the categories of persons who may have comprised a product development team, depending on the scope of the project. Additionally, Defendants have produced information to the Plaintiffs identifying the leaders of the various Product Development Teams, such as Karen Lessig, Dan Smith, John Young, and Katrin Elbert. It is anticipated that all of these witnesses will be deposed. Plaintiffs could refer during these depositions to the Team Meeting minutes and ask these team leaders what roles specific persons played on the various projects. Or the Plaintiffs could ask Defendants to identify particular individuals who played particular roles in a certain project (for example, who performed the bench-top testing on a specific project) and Defendants will provide that information to the Plaintiffs. But that is not the method of discovery Plaintiffs insist on, and the method Plaintiffs insist on does not comport with Rule 30(b)(6).

d. Topic i (Project Names for TVT Devices)

Topic "i" seeks testimony related to "All project names of the [TVT] devices." In their objections, Defendants properly pointed out that this information was already in Plaintiffs' possession, as it is included within the design history files, all of which Defendants have produced to Plaintiffs in the manner they were kept in the ordinary course of business and in an electronically searchable format. [517, p 7] However, Defendants also stated: "In an effort to compromise, Defendants will, in advance of the deposition, provide Plaintiffs with a list of the project names it has identified for the devices to date." [517, p. 7]

The list referenced in the Objection and which will be relied upon at the deposition is attached to this Response as Exhibit D. It was originally compiled by counsel through a review of the very documents that were provided to Plaintiffs in discovery (and referenced above) and it was subsequently reviewed by Defendants' designee on this topic who will be prepared to testify that it is, to the best of his knowledge, accurate. Thus, Plaintiffs' objection makes no sense: Defendants previously provided to the Plaintiffs the information that is responsive to this topic; Defendants, though they had no obligation to do so, created a document that summarized this information for Plaintiffs' benefit; and Defendants' corporate designee will be able to testify that this summary is, to the best of his knowledge, accurate. Prior to this Motion being filed, Defendants told Plaintiffs that they would do exactly what they have done. There is no dispute about this topic or if there is, Defendants do not understand what it is and it is certainly not valid as Defendants have exceeded their obligations under the Federal Rules.

e. Topic s (Patents)

1. US patents

Topic "s" seeks testimony related to "Any patents related to the [TVT] devices and their predecessor mesh products."

Prior to the filing of Defendants' Objections, Defendants engaged in a meet and confer with the Plaintiffs on March 22, 2013, and pointed out that the subject matter was so broad that no witness could address it. As a result of this meet and confer, Plaintiffs proposed to limit their area of inquiry to the following: "the identity of the inventor, the name of the patent holder, a description of the patent, and testimony regarding the patents for the device from a 'design perspective.'" [517, 10] In Defendants' Objections, Defendants pointed out that this information still fails to describe with reasonable particularity the matters for examination as

required by Rule 30(b). Defendants also stated: "In an effort to compromise, however, Defendants will produce a witness to testify about the United States patents directly related to the Devices. For each of these patents, Defendants' designee will be prepared to testify as a corporate representative regarding the identity of the inventor, the name of the present holder of each patent, and the patent's description. Additionally, the designee will be prepared to testify about the patents from a 'design perspective' and to his or her personal knowledge concerning each of the patents at issue." [517, p. 10] Thus, Defendants have agreed to do exactly what Plaintiffs suggested.

In addition to the witness's testimony set forth above, which would satisfy any obligation Defendants have in regard to Rule 30(b)(6), attached as Exhibit E is a set of documents that Defendants designee plans to rely on at the deposition and which include: a table of patents and abstracts; MicroPatent Reports; and the Patent Assignments for TVT Classic.

Again, Plaintiffs' argument makes no sense. Defendants have agreed to do exactly what Plaintiffs requested: Defendants' designee will be prepared to testify regarding the identity of the inventor, the name of the present holder of each patent, the patent's description, the patents from a 'design perspective,' and to his or her personal knowledge concerning each of the patents at issue. [517, p. 10] Again, there is no dispute on this topic or if there is, it is improper as Defendants are providing exactly what Plaintiffs stated they were seeking.

2. Predecessor Devices

 Secur, TVT Exact, and TVT-Abbrevo." [517, p. 10] Plaintiffs concede this in their Motion stating: "Plaintiffs agreed to be more specific and reformulated the topic to the devices identified in the 30(b)(6) deposition notices." [584, p. 13]

Thus, although Plaintiffs may now change their position and seek such information, and perhaps at some point this Court might find they are entitled to such information, such a request is not a proper topic for a motion to compel or for the deposition noticed for May 15 & 16, 2013.

3. Ex-US Patents

Plaintiffs next contend that they are entitled to testimony concerning ex-US patents. What Plaintiffs do not tell the Court is that the parties have been involved in extensive negotiations concerning what ex-US information and documents should be produced. Throughout the history of these negotiations, Defendants have maintained that they would produce truly relevant ex-US information, such as worldwide adverse event reports. However, to produce non-relevant information that relates solely to other countries is unduly burdensome and inappropriate.

In an effort to compromise, Defendants have agreed to produce regulatory information and marketing information from countries selected by Plaintiffs. However, to produce a witness to discuss patent information from numerous countries around the world concerning multiple products is unreasonable. As far as Defendants are aware, all Plaintiffs in this action received the products at issue in the United States. Accordingly, the United States patents are what is relevant. Other countries have different requirements and regulations, so what is contained in those patents is tailored to those countries, not the United States. Accordingly, ex-US patents are not a proper topic for this deposition. In any event, if this Court wants to address the issue of ex-

US documents in general, that is a far broader issue than the design 30(b)(6) and should be addressed by briefing directed solely at that issue and not as part of an expedited hearing.

f. Topic kk (Manufacturing Processes related to heating/extrusion/annealing/cooling/gamma radiation/sterilization)

Topic "kk" seeks testimony "As they relate to design control and validation, the manufacturing processes, including but not limited to heating / extrusion / annealing / cooling / gamma radiation / sterilization." Defendants properly lodged the following objection, clarification and agreement to produce on this topic:

Defendants object that: (a) it is impossible for any witness (or even multiple witnesses) to testify regarding the "the (sic) 'manufacturing processes' for all seven devices over a period of more than a dozen years; (b) this topic is dramatically overbroad since there will be numerous manufacturing processes related to the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular communications Plaintiffs seek to discover.

In the meet and confer held on March 22, 2013, Plaintiffs advised Defendants that this topic seeks testimony regarding the process by which the Prolene mesh is manufactured, woven, tested, and sterilized, as well as similar "type" information regarding the tools that accompany each device. As explained during that meet and confer, Defendants will produce a witness or witnesses who are knowledgeable about the manufacturing process in general and will be prepared to discuss this topic at a high level. To the extent Plaintiffs elect to drill down on a particular topic in greater detail, Defendants may have to identify additional witnesses to address those topics.

In order for Plaintiffs to file a motion to compel on this issue, there must be a dispute that is incapable of resolution without court intervention. L.R. Civ. P. 37.1(b). There is no such dispute at this time. Defendants have agreed to produce a witness or witnesses who can speak at a high level of detail regarding the manufacturing process and have agreed that if that is insufficient, that it may have to identify additional witnesses. There is nothing more that

Defendants can or should do in regard to this topic at this time. Accordingly, Plaintiffs' motion to compel with respect to Topic kk should be denied as unripe.

g. Request No. 5(n) (Procedures related to the Design History File)

Defendants have produced to Plaintiffs numerous SOPs that relate to the Design History File, including OP-650-006, which is the Operating Procedure for Design History File. Accordingly, Plaintiffs' motion with respect to Request No. 5(n) should be denied as moot.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs Motion should be denied.

Respectfully submitted,

ETHICON, INC. AND JOHNSON & JOHNSON

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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

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Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on May 13, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

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